

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response to Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 05/07/08 is acknowledged.

Claims 25, 27-29 and 31-39 are pending in this action. Claims 25, 33 and 34 have been amended herein by Applicant. Additionally, claim 34 has been amended via Examiner's Amendment. Claims 1-24, 26 and 30 have been cancelled. Claims 25, 27-29 and 31-39 are allowed.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Madsen on 18 July 18, 2008.

The application has been amended as follows:

#### In the Claims:

In claim 34, the claim dependency has been changed from "26" to ~~--25--~~.

***Allowable Subject Matter***

Claims 25, 27-29 and 31-39 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that Applicant's arguments filed on 05/07/08 on pages 6-7, with respect to the presence of excipients was found persuasive. Applicant states that "the 'consisting essentially of' language does not exclude composition or compounds, such as excipients (see spec. pg 5, lines 20-22). These arguments were found persuasive, in view of Applicant's disclosure regarding the presence of excipients. Accordingly, the 112, 2nd paragraph rejections have been withdrawn. Furthermore, Applicant has sufficiently overcome the 112, 1<sup>st</sup> paragraph rejection based on the amendment to claim 25.

The instant invention demonstrates an improvement over prior formulations, in that it provides for a controlled-release composition provided in a three-component matrix structure, (amphiphilic, lipophilic & hydrophilic matrices) whereby the plurality of systems enables control and modulation of the dissolution rate of active ingredients in aqueous and/or biological fluids, thereby controlling the release kinetics in the gastrointestinal tract.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

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